June 30, 2017

RE: Medical Policy, Clinical UM Guidelines, and Specialty Pharmacy changes notification letter

Dear Provider:

Anthem Blue Cross and Blue Shield and our subsidiary company, HMO Colorado (Anthem) are pleased to provide you with our updated and new medical policies. Anthem will also be implementing changes to our Clinical Utilization Management (UM) Guidelines that are adopted for Colorado. The Clinical UM guidelines published on our website represent the clinical UM guidelines currently available to all Plans for adoption throughout our organization. Because local practice patterns, claims systems and benefit designs vary, a local Plan may choose whether or not to implement a particular clinical UM guideline. The link below can be used to confirm whether or not the local Plan has adopted the clinical UM guideline(s) in question. Adoption lists are created and maintained solely by each local Plan.

The major new policies and changes are summarized below. Please refer to the specific policy for coding, language, and rationale updates and changes that are not summarized below.

New Medical Policies effective for service dates on and after October 1, 2017

- **MED.00121 Implantable Interstitial Glucose Sensors:** This document addresses the use of implantable interstitial glucose sensors (for example, the Eversense™ Continuous Glucose Monitoring System).
  - Use of implantable interstitial glucose sensors is considered Investigational & Not Medically Necessary for all indications.

- **MED.00122 Wilderness Programs:** This document addresses wilderness programs, including services such as adventure therapy or wilderness therapy when part of wilderness programs provided in an outdoor environment and proposed as a treatment option for a variety of medical conditions or behavioral health disorders.
  - Wilderness programs are considered Investigational & Not Medically Necessary for all indications.

- **SURG.00148 Spectral Analysis of Prostate Tissue by Fluorescence Spectroscopy:** This document addresses the use of spectral analysis of prostate tissue by fluorescence spectroscopy, which involves using fiber optics to differentiate between normal prostate tissue and suspicious prostate tissue.
  - Spectral analysis of prostate tissue by fluorescence spectroscopy is considered Investigational & Not Medically Necessary for all indications.

- **SURG.00149 Percutaneous Ultrasonic Ablation of Soft Tissue:** This document addresses the use of percutaneous ultrasonic ablation (emulsification) of soft tissue for the treatment of any condition.
  - Percutaneous ultrasonic ablation of soft tissue is considered Investigational & Not Medically Necessary for the treatment of any condition, including, but not limited to any of the following musculoskeletal conditions:
    A. Achilles tendinosis; or
    B. Lateral or medial elbow tendinosis; or
    C. Patellar tendinosis; or
    D. Recalcitrant plantar fasciitis; or
    E. Rotator cuff or shoulder tendinosis
- **SURG.00150 Leadless Pacemakers:** This document addresses a single chamber implantable transcatheter pacing system to monitor and regulate the heart rate and rate-responsive bradycardia.
  - Use of the leadless pacemaker is considered Investigational & Not Medically Necessary for all applications.

**Revised Medical Policies and Adopted Clinical UM Guidelines effective October 1, 2017:**

- **DRUG.00062 Obinutuzumab (Gazyva®):** This document addresses the indications and criteria for the use of obinutuzumab (Gazyva).
  - Clarified that obinutuzumab is Medically Necessary as a first-line treatment of CLL/SLL without del(17P) mutation when used in combination with chlorambucil.
  - Revised Medically Necessary criteria for the treatment of follicular lymphoma by adding additional chemotherapy regimens to be used in combination with obinutuzumab.

- **GENE.00001 Genetic Testing for Cancer Susceptibility:** This document addresses genetic testing to determine whether an individual is at risk for the development of cancer based on a genetic test.
  - Added Medically Necessary criteria regarding genetic counseling.

- **GENE.00002 Preimplantation Genetic Diagnosis Testing:** This document addresses the use of preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) which is performed as part of an assisted reproductive procedure.
  - Revised the first Medically Necessary statement to be “screening” instead of “diagnosis”.
  - Moved Medically Necessary criteria regarding balanced translocation to the Medically Necessary statement addressing diagnosis.
  - Clarified Medically Necessary position statement regarding “gender selection” to replace the term “gender” with “sex”.
  - Added Medically Necessary criteria regarding genetic counseling.

- **GENE.00007 Cardiac Ion Channel Genetic Testing:** This document addresses genetic testing of cardiac ion channel mutations in persons with suspected channelopathies, such as long QT syndrome (LQTS), in order to determine the risk for sudden cardiac death (SCD).
  - Added Medically Necessary criteria regarding genetic counseling.
  - Made minor language changes in position statement.

- **GENE.00012 Preconception or Prenatal Genetic Testing of a Parent or Prospective Parent:** This document addresses preconception or prenatal genetic testing on a parent or prospective parent to determine carrier status of an autosomal recessive disorder, an x-linked disorder, or a disorder with variable penetrance.
  - Revised title.
  - Added "familial dysautonomia" as a Medically Necessary indication when criteria met for preconception or prenatal genetic screening of a parent or prospective parent to determine carrier status of inherited disorders.
  - Revised Medically Necessary position statement for cystic fibrosis carrier screening to address using a standard panel usually consisting of 23 or more of the common gene mutations.
  - Added Not Medically Necessary position statements for use of: a) complete DNA sequencing of the cystic fibrosis transmembrane conductance regulator (CFTR) gene; b) gene analysis of known CFTR familial variants; and c) gene analysis of CFTR duplication/deletion variants to determine cystic fibrosis carrier status.
- Added Medically Necessary position statement to address genetic screening to determine carrier status of spinal muscular atrophy.
- Added Medically Necessary criteria regarding genetic counseling.
- Made minor language and formatting changes in position statement.

- **GENE.00017 Genetic Testing for Diagnosis and Management of Hereditary Cardiomyopathies (including ARVD/C):** This document addresses genetic testing for the hereditary cardiomyopathies which includes hypertrophic (HCM), dilated (DCM), restrictive (RCM), arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) and left ventricular noncompaction (LVNC).
  - Added Medically Necessary criteria regarding genetic counseling.

- **GENE.00026 Cell-Free Fetal DNA-Based Prenatal Testing:** This document addresses cell-free fetal DNA-based prenatal testing for fetal aneuploidies (including fetal sex chromosome aneuploidies), fetal sex determination and microdeletions.
  - Added Medically Necessary criteria regarding genetic counseling.

- **GENE.00028 Genetic Testing for Colorectal Cancer Susceptibility:** This document addresses genetic testing for individuals who are at higher than average risk for the development of colorectal cancer.
  - Added Medically Necessary criteria regarding genetic counseling.
  - Reformatted Medically Necessary criteria.

- **GENE.00029 Genetic Testing for Breast and/or Ovarian Cancer Syndrome:** This document addresses genetic testing for individuals who are at higher than average risk for the development of breast and/or ovarian cancer.
  - Added Medically Necessary criteria regarding genetic counseling.
  - Updated formatting.

- **GENE.00030 Genetic Testing for Endocrine Gland Cancer Susceptibility:** This document addresses genetic testing for individuals who are at higher than average risk for the development of endocrine gland cancer, including medullary thyroid cancer.
  - Added Medically Necessary criteria regarding genetic counseling.
  - Updated formatting.

- **GENE.00031 Genetic Testing for PTEN Hamartoma Tumor Syndrome:** This document addresses mutation testing of the phosphatase and tensin homolog (PTEN) gene.
  - Added Medically Necessary criteria regarding genetic counseling.
  - Updated formatting.

- **GENE.00035 Genetic Testing for TP53 Mutations:** This document addresses genetic testing for TP53 mutations.
  - Added Medically Necessary statement for use of TP53 gene mutation testing for individuals diagnosed with hypodiploid acute lymphocytic leukemia when criteria met.
  - Added Medically Necessary criteria regarding genetic counseling.

- **GENE.00040 Genetic Testing for CHARGE Syndrome:** This document addresses genetic testing for CHARGE syndrome, a rare genetic condition associated with multiple congenital anomalies.
  - Added Medically Necessary criteria regarding genetic counseling.
- **GENE.00043 Genetic Testing of an Individual’s Genome for Inherited Diseases**: This document addresses the framework for consideration of genetic testing for any disease with an established genetic basis.
  - Added Medically Necessary criteria regarding genetic counseling.

- **CG-DRUG-29 Hyaluronan Injections in the Knee**: This document addresses the use of hyaluronan injections for the replacement or supplementation of naturally occurring intra-articular lubricants in individuals with osteoarthritis in the knees (also referred to as viscosupplementation).
  - Revised the use of hyaluronan injections for osteoarthritis in the knees from Medically Necessary to Not Medically Necessary.

**Reminder – Specialty pharmacy program includes utilization review of clinically equivalent agents as of June 1, 2017**

On **February 1, 2017** and **March 31, 2017** Anthem shared information about the expansion of the specialty pharmacy program to include reviews for clinically equivalent agents beginning with dates of service on and after June 1, 2017. As a reminder, we are sharing details about this change for ease of reference. **Please note that the Hyaluronan injections CG-DRUG-29 and DRUG.00017 are no longer part of this program and therefore will not be reviewed as part of clinically equivalent agent management.**

<table>
<thead>
<tr>
<th>Medical Policy or Clinical UM Guideline number</th>
<th>Impacted Products</th>
<th>Clinically Equivalent/Cost Effective Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-Approved Biosimilar Products; CG-DRUG-64</td>
<td>Inflectra®</td>
<td>Remicade®</td>
</tr>
</tbody>
</table>

For more information on Anthem Medical Policy and Clinical UM guidelines and dosing guidelines refer to the complete list of our Medical Policies and Clinical UM Guidelines that are accessed on Anthem’s provider web site at Anthem.com. (See navigation instructions later in this notification).

**Reminder – Specialty pharmacy program expands to include utilization review of drug dosage and frequency beginning September 1, 2017**

On **February 1, 2017** Anthem shared information about the expansion of the specialty pharmacy program to include reviews for drug dosage and frequency. Please note that the implementation of the new clinical guideline **Drug Dosage, Frequency, and Route of Administration CG-DRUG-53** was delayed, but will begin with dates of service on and after September 1, 2017. As a reminder, we are sharing the details about this upcoming change for ease of reference.

Beginning with dates of service on and after September 1, 2017, a new clinical guideline **Drug Dosage, Frequency, and Route of Administration CG-DRUG-53** will apply to the review process for Specialty Pharmacy. The expanded program will continue to be administered by AIM Specialty Health® (AIM), a separate company. Based on the information you provide, AIM will review the drug for clinical appropriateness, drug dosage, and frequency against health plan clinical criteria.

As part of pre cert process the following information will be required:

1. Weight, height, age, gender
2. Dosage per treatment, directions per treatment (frequency), and duration (length of therapy)

The expanded program applies to members who have specialty pharmacy services medically managed by AIM.

**To ensure accurate and timely payment, it is important that you provide the above requested information effective September 1, 2017.**
All changes referenced in this letter only apply to Local Plan members. They do not apply to BlueCard out-of-area, selected National Accounts, Medicare, Medicare Advantage (MA), or Federal Employee Plan (FEP) members.

**Note:** If the service is not prior authorized/pre-certified, records will be requested for post service review based on the same criteria listed in the medical policy or clinical guideline.

**Providers will continue to request authorization for specialty drugs in one of several ways:**

- Access AIM ProviderPortalSM directly at [providerportal.com](http://providerportal.com). Online access is available 24/7 to process orders in real-time, and is the fastest and most convenient way to request authorization.
- Access AIM via the Availity Web Portal at [availity.com](http://availity.com).
- Call the AIM Contact Center toll-free number: 877-291-0366

**Note:** Retrospective requests received more than 2 business days after the date of service will not be accepted by AIM for precertification review. Any post-service clinical review would be handled by Anthem according to the terms of the applicable health benefit plan and/or provider agreement.

For more information on our medical policy and dosing guidelines, refer to the complete list of medical policies and clinical UM guidelines that are available on our provider website at anthem.com.

Anthem Medical Policies and Clinical UM Guidelines are developed by our national Medical Policy and Technology Assessment Committee. The Committee, which includes Anthem medical directors and representatives from practicing physician groups, meets quarterly to review current scientific data and clinical developments.

All coverage written or administered by Anthem excludes from coverage, services or supplies that are investigational and/or not medically necessary. A member’s claim may not be eligible for payment if it was determined not to meet medical necessity criteria set in Anthem’s medical policies. Review procedures have been refined to facilitate claim investigation.

**Anthem’s Medical Policies and Clinical UM Guidelines are available online:**

The complete list of our Medical Policies and Clinical UM Guidelines may be accessed on Anthem’s Web site at [anthem.com](http://anthem.com). Select Provider link (top center of page), then Colorado (from the drop down list), and enter. On the Provider Home page, from the Medical Policy, Clinical UM Guidelines, Pre-Cert Requirements tout (2nd blue box on the left side of page), select enter. Click on the link titled “Medical Policies and Clinical UM Guidelines (for Local Plan Members)”. Click Continue, then select the either the Medical Policies or the UM Guidelines tab.

To view the list of specific clinical UM guidelines adopted by Colorado, navigate to the Disclaimer page by following the instructions above; scroll to the bottom of the page. Above the “Continue” button, click on the link titled “Specific Clinical UM Guidelines adopted by Anthem Blue Cross and Blue Shield of Colorado.”

Sincerely,

Elizabeth Kraft, M.D.
Medical Director
Anthem Blue Cross and Blue Shield

Enclosure: Attachment A
## Attachment A – Revised Medical Policies and Clinical Guidelines

<table>
<thead>
<tr>
<th>Medical Policy Number</th>
<th>Medical Policy Title</th>
<th>Medical Policy / Clinical Guideline Changes</th>
</tr>
</thead>
</table>
| DRUG.00006            | Botulinum Toxin                                                                      | • Revised scope of document.  
• Moved position statement and language addressing treatment of hyperhidrosis with botulinum toxin from MED.00032.  
• Removed of Investigational & Not Medically Necessary indications from the Clinically Equivalent Cost Effective Agents (CECEA) section. |
| DRUG.00041            | Rituximab (Rituxan®) for Non-Oncologic Indications                                   | • Added Medically Necessary statement for use of rituximab in relapsing-remitting form of multiple sclerosis when criteria are met.  
• Revised Investigational & Not Medically Necessary statement for multiple sclerosis, adding “other than relapsing forms (such as, primary progressive or secondary progressive)”. |
| DRUG.00047            | Brentuximab Vedotin (Adcetris®)                                                     | • Added Medically Necessary statement for the use of brentuximab vedotin as a treatment for individuals with any of the following indications: Hodgkin lymphoma as maintenance therapy when criteria are met; Hodgkin lymphoma as a single-agent, palliative treatment when criteria are met; CD30+ non-Hodgkin lymphoma as a single-agent for adult T-cell leukemia/lymphoma when criteria are met; and CD30+ non-Hodgkin lymphoma for breast implant-associated anaplastic large cell lymphoma when criteria are met.  
• Reformatted Medically Necessary criteria. |
| DRUG.00066            | Antihemophilic Factors and Clotting Factors                                          | • Revised Medically Necessary statements for antihemophilic factor (factor VIII) recombinant, pegylated (Adynovate) to include children and perioperative management.  
• Added prophylaxis Medically Necessary criteria for Alphanate and Humate-P  
• Added Xyntha to the prophylaxis MN criteria for antihemophilic factor (factor VIII) recombinant. |
| DRUG.00071            | Pembrolizumab (Keytruda®)                                                            | • Added Medically Necessary statement for the use of pembrolizumab for the treatment of individuals with colorectal cancer when criteria met.  
• Revised Medically Necessary statement for head and neck squamous cell carcinoma (HNSCC), no longer requiring criteria requirement for PD-L1 gene expression.  
• Reformatted Medically Necessary criteria. |
| DRUG.00075            | Nivolumab (Opdivo®)                                                                  | • Added Medically Necessary statement for the use of nivolumab for the treatment of individuals with colorectal cancer when criteria met.  
• Added Medically Necessary statement for use of nivolumab for the treatment of individuals with locally advanced or metastatic urothelial carcinoma when criteria are met.  
• Revised Investigational & Not Medically Necessary statement for reason of treatment other than for diagnosis with accompanied criteria noted above.  
• Reformatted Medically Necessary criteria. |
<p>| GENE.00003            | Genetic Testing and Biochemical Markers for the Diagnosis of Alzheimer's Disease     | • Revised and had no significant changes to the policy position or criteria. |
| GENE.00005            | BCR-ABL Mutation Analysis                                                            | • Revised and had no significant changes to the policy position or criteria. |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENE.00006</td>
<td>Epidermal Growth Factor Receptor (EGFR) Testing</td>
<td>• Clarified Medical Necessity statement regarding EGFR testing for individuals undergoing TKI inhibitor therapy.</td>
</tr>
<tr>
<td>GENE.00009</td>
<td>Gene-Based Tests for Screening, Detection and Management of Prostate Cancer</td>
<td>• Revised and had no significant changes to the policy position or criteria.</td>
</tr>
<tr>
<td>GENE.00016</td>
<td>Gene Expression Profiling for Colorectal Cancer</td>
<td>• Revised and had no significant changes to the policy position or criteria.</td>
</tr>
<tr>
<td>GENE.00022</td>
<td>In Vitro Companion Diagnostic Devices</td>
<td>• Revised and had no significant changes to the policy position or criteria.</td>
</tr>
<tr>
<td>GENE.00023</td>
<td>Gene Expression Profiling of Melanomas</td>
<td>• Revised and had no significant changes to the policy position or criteria.</td>
</tr>
</tbody>
</table>
| GENE.00032 | Molecular Marker Evaluation of Thyroid Nodules                              | • Added Medically Necessary statement for the use of a gene expression classifier for molecular marker evaluation of a thyroid nodule for use with fine needle aspirates, after initial cytopathology is indeterminate (that is, atypia of undetermined significance (AUS), follicular lesion of undetermined significance (FLUS), suspicious for follicular neoplasm (SFN), follicular neoplasm (FN), and suspicious for malignancy.  
• Added Investigational & Not Medically Necessary statement for repeat testing of the same nodule and when the Medically Necessary criteria are not met. |
| GENE.00038 | Genetic Testing for Statin-Induced Myopathy                                | • Revised and had no significant changes to the policy position or criteria.                                                                |
| GENE.00045 | Detection and Quantification of Tumor DNA Using Next Generation Sequencing in Lymphoid Cancers | • Revised and had no significant changes to the policy position or criteria.                                                                |
| MED.00032 | Treatment of Hyperhidrosis                                                 | • Revised scope of document.  
• Moved position statement and all other language addressing treatment of hyperhidrosis with botulinum toxin to DRUG.00006. |
| RAD.00043 | Computed Tomography Scans for Lung Cancer Screening                         | • Revised title.  
• Updated formatting.                                                                                                                     |
| RAD.00060 | Digital Breast Tomosynthesis                                                | • Archived effective 02/20/2017.                                                                                                           |
| CG-DME-01 | External (Portable) Continuous Insulin Infusion Pumps                       | • Clarified Medically Necessary criteria for replacement pumps.                                                                             |